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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,565	01/29/2004	Karla Weaver	706181-2001	6338

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Bingham McCutchen LLP
2020 K Street, NW
Washington, DC 20006

EXAMINER

STIGELL, THEODORE J

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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12/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/768,565	Applicant(s) WEAVER ET AL.	
	Examiner THEODORE J. STIGELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Appeal Brief

The rejection of claims 1-9 and 17-21 under 35 U.S.C. 102(b) as anticipated by Mikhail (US 5,707,357) has been affirmed (see Board decision mailed on 9/2/2009). Accordingly, the rejection of claims 1-9 and 17-21 as anticipated by Mikhail will be maintained.

The rejection of claims 10-16 under 35 U.S.C. 102(b) as anticipated by Mikhail (US 5,707,357) has been reversed (see Board decision mailed on 9/2/2009). Accordingly, the rejection of claims 10-16 as anticipated by Mikhail will be withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 and 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mikhail (US 5,707,357).

In regards to claim 1, Mikhail discloses a pressure actuated valve (36) for controlling the flow of fluid through a medical device (10) comprising a housing (14) including a lumen extending therethrough, and a flow control membrane (38) extending across the lumen to control the flow of fluid through the lumen, the membrane including a plurality of slits (76, see at least Figures 21-35) extending therethrough, wherein when

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the membrane is acted upon by a pressure of at least a threshold magnitude (the examiner is interpreting "pressure" to mean any type of force exerted upon a surface including a force exerted by fluid and squeezing, etc.), the slits open to permit flow through the lumen (see col. 22, lines 38-62) and, when not acted upon by a pressure of at least the predetermined magnitude, the slits are maintained closed by the biasing force applied thereto by the membrane to prevent flow through the lumen (valve 36 is normally biased in a closed position), wherein each of the slits extends between end portions thereof along a curve (there are multiple embodiments in Figs. 21-35 with a plurality of curved slits, see at least Figs. 32 and 33) and wherein a distance between a first end portion of one slit and the first end portions a second slit is the minimum distance between the first and second slits (the examiner is defining the "end portions" of the slits as the area between points A and B in the figure shown below, at point B of the end portion is smallest distance between the two slits). See drawing shown in the Examiner's Answer mailed on 2/26/2008.

In regards to claims 2-9, Mikhail discloses a valve wherein the first slit extends along a portion of a curve and the second slit extends along a portion of a curve which is substantially a mirror image of the curve (see at least Figs. 28 or 31), and wherein the valve further includes a third slit with a different radius of curvature (see at least Fig. 28), wherein the first and second slits are disposed symmetrically about a line of symmetry (see at least Figs. 28 and 31), wherein the membrane can be elliptical or circular (see column 27, lines 60-67), and wherein the first and second slits are spaced

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from one another so that the edges of each slit do not contact each other under any condition.

Claims 17-19 recite substantially the same limitations as claims 1-16 and therefore the examiner maintains the same interpretation provided above. Claim 17 does further recite that the device is a dialysis catheter which the examiner is not assigning much patentable weight thereto. The Mikhail device could be used as a crude dialysis catheter if it had to be. In regards to claims 19, the examiner is interpreting these limitations to be mostly functional. There is no specific magnitude recited that corresponds to the "pressure" exerted by the dialysis machine and therefore the "pressure" could be any pressure. The examiner maintains that there is a fluid pressure that is capable of opening the slits (76) as this feature is inherent to almost any medical slit valve.

Claims 19-21 recite substantially the same structural limitations as claims 1-19 and therefore the examiner maintains the same interpretation provided above. Claims 19-20 further recite that the pressure is a "flow pressure". The examiner maintains that there is a flow pressure strong enough to open the slits (76) of Mikhail even though Mikhail is not necessarily designed to operate in such a manner.

Claims 10-11, 13, 17, 19, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones (US 2,720,881).

Jones discloses a flow control device (1) comprising a substantially planar elastic membrane (3) including a central portion (8) including a curved slit (7) extending

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therethrough, wherein the membrane is biased in a closed configuration and is capable of opening upon a predetermined fluid pressure.

Claims 10-11, 13, 17, 19, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Weaver et al. (US 7,435,236)

Weaver discloses a flow control device comprising a substantially planar elastic membrane (350) including a central portion including a curved slit (362) extending therethrough, wherein the membrane is biased in a closed configuration and is capable of opening upon a predetermined fluid pressure.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daly et al. (US 2004/0186444).

Daly discloses a pressure actuated valve (110) including a flow control membrane (body of 110) extending across a lumen of a housing (105) wherein the membrane includes a plurality of slits (192, 193) that are configured to be in a closed configuration until acted upon by a predetermined fluid pressure. Daly fails to specifically teach a curved slit configuration but does teach that other suitable shaped slits are within the scope of the invention (see paragraph [0042]). The curved slit configuration is therefore deemed to be a design consideration that fails to patentably distinguish over the prior art. A change in the shape of a prior art device is a design consideration within the skill of the art. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

The applied reference has a common inventor with the instant application.
Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

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the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

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